IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BLUE CROSS BLUE SHIELD ASSOCIATION, et al.	:	CIVIL ACTION
	:	No. 13-4663
v.	:	
GLAXOSMITHKLINE LLC	:	

MEMORANDUM

Juan R. Sánchez, J. **November 9, 2016**

Plaintiffs, 41 private health insurance companies that purchased billions of dollars' worth of adulterated pharmaceutical drugs from Defendant GlaxoSmithKline LLC (GSK), bring claims against GSK under the Racketeer Influenced and Corrupt Organizations Act (RICO) and Pennsylvania law, alleging they purchased the drugs at issue based on GSK's misrepresentations that the drugs were manufactured in accordance with federal safety and quality practices. Plaintiffs claim the adulterated drugs were worthless and had they known of the adulteration they would not have included the drugs in their formularies. GSK moves to dismiss Plaintiffs' Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) on grounds that (1) Plaintiffs have not adequately alleged a cognizable injury to establish standing and (2) all claims are barred by the applicable statute of limitations. GSK also moves to dismiss Plaintiffs' claims pertaining to the drug Paxil CR from April 1, 2002, through March 4, 2005, as barred by its 2009 class action settlements. Because Plaintiffs have adequately pleaded an injury for purposes of standing, and because the merits of the statute of limitations defense turn on factual issues that

cannot be resolved at this stage, GSK's motion to dismiss the complaint for failure to state a claim will be denied.[1]

BACKGROUND[2]

Under federal law, pharmaceutical drugs must be manufactured in accordance with "current Good Manufacturing Practices" (cGMPs) to assure they meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B). The cGMPs are codified in 21 C.F.R. Parts 210 and 211, and are enforced by the Food and Drug Administration (FDA). Any drug not manufactured in accordance with cGMPs is deemed "adulterated"[3] and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B).

Between 1997 and 2006, GSK distributed and sold large quantities of adulterated drugs in the U.S. market. All of the drugs at issue[4] were manufactured at a plant in Cidra, Puerto Rico,

[1] GSK filed its motion to dismiss on October 11, 2013. While the motion was pending, the Third Circuit agreed to hear an interlocutory appeal in another case raising a similar issue regarding RICO standing. *See In re Avandia Marketing, Sales Practices & Products Liability Litigation*, No. 10-5419, 2013 WL 5761202 (E.D. Pa. Oct. 23, 2013). On May 5, 2014, the Court stayed and put this case in suspense pending the resolution of that appeal. The Third Circuit decided *In re Avandia* on October 26, 2015, and the parties in this case then filed briefs addressing the impact of the decision on GSK's motion to dismiss.

[2] The following facts are drawn from Plaintiffs' Complaint, the well-pleaded factual allegations of which this Court must accept as true in evaluating the instant motion to dismiss. *See Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009).

[3] Drugs are deemed to be adulterated if the manufacturer fails to comply with cGMPs to assure the drugs' safety, quality, purity, identity, and strength and/or if they are contaminated. *See* 21 U.S.C. § 351(a)(2)(A), (B). Federal law prohibits a manufacturer from directly or indirectly causing adulterated drugs to be introduced or delivered for introduction into interstate commerce. *See id.* § 331(a).

[4] The at-issue drugs in this case include Paxil, Paxil OS, Avandia, Avandamet, Coreg, Bactroban, Kytril, Compazine, Denavir, Dyazide, Dibenzyline, Thorazine, Stelazine, Relafen, Factive, Dyrenium, and Albenza. Compl. ¶ 3. Only some of these drugs—Avandamet, Kytril, Bactroban, and Paxil CR—were found by the FDA to be adulterated. Nevertheless, Plaintiffs

that was owned and operated by SB Pharmco Puerto Rico, Inc., a wholly owned subsidiary of GSK. The Cidra plant was riddled with chronic and pervasive manufacturing and quality problems that violated numerous cGMPs and affected the integrity of all of the drugs manufactured there. Both GSK and SB Pharmco were aware of these problems, and deliberately cut corners to maximize profits.

The FDA inspected the Cidra plant in 2001, finding significant deficiencies, but determined that GSK was responding adequately to those deficiencies. After another inspection in 2002 that revealed persistent cGMP violations, the FDA issued a Warning Letter[5] to Cidra. GSK responded to the letter by committing to take specific acts to address the violations and assigned the company's Manager of Global Quality Assurance, Cheryl Eckard, to lead a team to ensure those commitments were fulfilled. Throughout 2002 and 2003, Eckard urged GSK management to take action regarding ongoing violations at the Cidra plant. In April 2003, Eckard submitted to GSK executives a report documenting and summarizing the history of cGMP violations at the Cidra plant. The report noted certain high-risk compliance problems and called for increased monitoring by GSK management of compliance improvement initiatives. Eckard's concerns were not addressed, and she was terminated the following month.

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claim that because the Cidra plant was chronically in violation of FDA regulations, all of the at-issue drugs were adulterated.

[5] The FDA issues "Warning Letters" to achieve voluntary compliance and to establish prior notice" before initiating enforcement action. U.S. Food & Drug Administration, *4.1 Warning Letters*, http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176870.htm (last visited Oct. 31, 2016). Warning Letters are "issued only for violations of regulatory significance." *Id.*

Following her termination, Eckard informed the FDA of GSK's unwillingness to address the ongoing deficiencies in the Cidra plant.[6] The FDA ultimately commenced a criminal investigation, and in March 2005 seized all stocks of two drugs manufactured at the Cidra plant, Avandamet and Paxil CR. The following month, the FDA and GSK entered into a consent decree, and the FDA permanently enjoined GSK from directly or indirectly introducing or delivering into interstate commerce any adulterated product from the Cidra plant. In late 2007, GSK announced it would shut down the Cidra plant, which ultimately closed in late 2009. In 2010, SB Pharmco pleaded guilty to the federal crime of introducing into interstate commerce, with intent to defraud and mislead, adulterated versions of four of the drugs manufactured at the Cidra plant, Advandamet, Kytril, Bactroban, and Paxil CR, in violation of 21 U.S.C. §§ 331(a), 333(a)(2), and 351(a)(2)(B). Plaintiffs allege that the adulteration extended to all of the drugs manufactured at the Cidra plant.

In July 2013, Plaintiffs filed their Complaint in state court alleging GSK violated federal and state law by fraudulently inducing Plaintiffs to pay billions of dollars for the adulterated drugs. The next month, GSK removed this case to federal court. Plaintiffs bring nine causes of action: (1) three Racketeer Influenced and Corrupt Organizations Act (RICO) violations under 18 U.S.C. § 1962(c) and (d); (2) common law fraud; (3) civil insurance fraud under 18 Pa. Cons. Stat. § 4117; (4) breach of express warranty under 13 Pa. Cons. Stat. § 2313; (5) breach of the implied warranty of merchantability under 13 Pa. Cons. Stat. § 2314; (6) common law unjust

[6] Eckard also brought a qui tam suit under the False Claims Act in 2004, which was later joined by the Department of Justice. GSK eventually settled the suit for $600 million. *See* Pl.'s Rico Case Stmt. 5 (citing *United States ex rel. Eckward v. SmithKline Beacham Corp., d/b/a/ GlacoSmithKline, et al.*, No. 04-CV-10375-JLT (D. Mass.)).

enrichment; and (7) common law negligent misrepresentation. GSK argues all of Plaintiffs' claims should be dismissed for failure to state a claim.

DISCUSSION

To survive a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible when the facts pleaded "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* Although the plausibility standard "is not akin to a 'probability requirement,'" the complaint must support "more than a sheer possibility that a defendant has acted unlawfully." *Id.* (citation omitted). A complaint which "pleads facts that are merely consistent with a defendant's liability . . . stops short of the line between possibility and plausibility of entitlement to relief." *Id.* (quoting *Twombly*, 550 U.S. at 557) (internal quotation marks omitted). In evaluating a complaint's sufficiency under these standards, a court must first "tak[e] note of the elements a plaintiff must plead to state a claim." *Santiago v. Warminster Twp.*, 629 F.3d 121, 130 (3d Cir. 2010) (quoting *Iqbal*, 556 U.S. at 675). Next, the court should "identify allegations that, 'because they are no more than conclusions, are not entitled to the assumption of truth.'" *Id.* (quoting *Iqbal*, 556 U.S. at 679). Finally, where there are well pleaded allegations, the court "should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Id.* (quoting *Iqbal*, 556 U.S. at 679).

A. Paxil CR Claims

GSK asserts Plaintiffs' claims related to their purchases of Paxil CR between April 1, 2002, and March 4, 2005, are barred by two 2009 class action settlements. Def.'s Mot. to

Dismiss 26-27. Plaintiffs contend GSK's argument is irrelevant because the only Paxil-related claims concern Paxil and Paxil OS, not Paxil CR. *See* Compl. ¶ 3. Although Plaintiffs do not list Paxil CR as an at-issue drug, they do reference Paxil CR in their Complaint with regards to "GSK's wrongdoing." *See* Compl. ¶¶ 4 (noting SB Pharmco's federal guilty plea concerned the proliferation of adulterated versions of Paxil CR), 110 (describing a March 2005 FDA seizure of all stocks of Avandamet and Paxil CR). To the extent Plaintiffs' claims relate to their purchases of Paxil CR between April 1, 2002, and March 4, 2005, the Court will not consider Paxil CR in its analysis of the instant motion, and any purchases of Paxil CR between April 1, 2002, and March 4, 2005, will not be considered for purposes of damages.

B. Standing

GSK argues the Complaint should be dismissed because Plaintiffs have failed to sufficiently allege a cognizable injury—a necessary element of each of Plaintiffs' claims. Although Plaintiffs allege they suffered a cognizable injury by paying for the adulterated at-issue drugs, GSK argues Plaintiffs cannot demonstrate an actual injury because they do not allege the at-issue drugs were unsafe or ineffective.[7]

To pursue a civil action under RICO, a plaintiff must first establish standing under Section 1964(c), which provides:

> Any person injured in his business or property by reason of a violation of section 1962 of this chapter may sue therefore in any appropriate United States district court and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney's fee . . . .

[7] As the same injury is alleged with respect to all claims, and because the parties do not argue that the respective injury standards for Plaintiffs' remaining claims differ in any material way, the Court will follow suit and analyze the injury issue in a RICO framework. *See Toll Bros. v. Twp. of Readington*, 555 F.3d 131, 139 n.5 (3d Cir. 2009).

Thus, a RICO plaintiff must make a threshold showing that it has "suffered an injury to business or property and that [the] injury was caused by the defendant's violation of 18 U.S.C. § 1962." *In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, 804 F.3d 633, 638 (3d Cir. 2015) (citing *Maio v. Aetna, Inc.*, 221 F.3d 472, 482 (3d Cir. 2000)). To establish an injury to business or property, a plaintiff must allege and prove "actual monetary loss, i.e., an out-of-pocket loss." *Maio*, 221 F.3d at 483.

Prior to the Third Circuit's decision in *In re Avandia*, district courts in this Circuit followed *Maio* in analyzing an insurer's standing to pursue claims relating to the purchase of misrepresented drugs. In *Maio*, the Third Circuit held health insurance beneficiaries had not alleged a cognizable RICO injury against their insurer, Aetna, when they alleged Aetna's misrepresentations regarding the services included in their HMO plans caused them to "pay too much in premiums for an 'inferior' health care product." 221 F.3d at 484-85. Because the plaintiffs' alleged injury was premised solely on the possibility they would receive inferior care in the future and not on past substandard care, the Court found the plaintiffs failed to plead a tangible economic injury where they provided "no factual basis for [the] conclusory allegation" that the insurance coverage was "worth less" than what the plaintiffs had paid for it. *Id.* at 490. District courts have interpreted *Maio* to bar insurers' claims where there were no specific allegations that the at-issue drugs were proven to be unsafe or ineffective. *See In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 06-CV-5774, 2009 WL 2043604, at *18 (D.N.J. July 10, 2009) (finding *Maio* "directly on point" in case involving alleged overpayment for misrepresented drugs); *Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, No. 06-3044, 2008 WL 5413105, at *7 (D.N.J. Dec. 23, 2008) (finding plaintiffs were

"assert[ing] a substantially similar 'overpayment' argument as that made by the unsuccessful plaintiffs in *Maio*").[8]

The Third Circuit distinguished *Maio* in *In re Avandia*, in which the plaintiff-insurers alleged GSK deliberately misrepresented and concealed the safety risks associated with a diabetes drug, causing them to include the drug in their formularies and cover the drug at favorable rates. 804 F.3d at 636. The plaintiffs alleged two theories of injury: (1) the at-issue drug was worth less than the favorable rates at which they covered it (the "excess price" theory); and (2) physicians relied on GSK's misrepresentations in deciding to prescribe the at-issue drug to more patients that they would have had GSK not concealed the risks of the drug (the "quantity effect" theory). *Id.* The Court of Appeals affirmed the district court's denial of GSK's motion to dismiss, finding the insurers' alleged injury—prioritizing the drug on their formularies and overpaying for the drug due to GSK's illegal or deceptive marketing practices—was a concrete economic harm. *Id.* at 640. That concrete injury, cognizable under RICO, was distinguishable from the injury in *Maio*, which was based on contingent future events concerning the quality of health care. *Id.*

In reaching its decision, the Third Circuit relied on *In re Warfarin Sodium Antitrust Litigation*, 391 F.3d 516 (3d Cir. 2004), which "offer[ed] the closest analogy" to the facts before it. *Id*. In *In re Warfarin*, the plaintiff-insurers alleged the defendant engaged in anticompetitive behavior and disseminated false and misleading information about a low-priced, readily available generic competitor, causing the plaintiffs to purchase the higher-priced brand name drug instead. 391 F.3d at 521. In affirming the district court's approval of a class action settlement, the Court of Appeals rejected an argument that the insurers did not have standing to assert antitrust claims,

[8] These cases generally deal with allegations of fraud and misrepresentation by defendant-drug companies engaged in off-label marketing which is prohibited by the FDA.

finding "it well recognized that a purchaser in a market where competition has been wrongfully restrained has suffered an antitrust injury."[9] *Id.* at 531. The *In re Avandia* court concluded that, just as the "injury suffered by the [*Warfarin* plaintiffs] did not depend on the drug's ineffectiveness but rather on the defendant's anticompetitive behavior[,] . . . the injury suffered by the [third-party payers] in this case does not depend on Avandia's effectiveness, but rather on GSK's fraudulent behavior." 804 F.3d at 640.

Under *In re Avandia*, an insurer's overpayment for a drug due to the manufacturer's deceptive market practices is a concrete economic injury. Plaintiffs have sufficiently pleaded an analogous injury here. Plaintiffs allege GSK caused injury to their business and property because they justifiably relied on GSK's fraudulent material misrepresentations and omissions in placing "adulterated," and effectively "worthless," drugs on their formularies and subsequently paying for those drugs. Compl. ¶¶ 6-7. Plaintiffs allege that but for GSK's fraudulent concealment of the myriad ongoing regulatory violations at the Cidra plant, and GSK's misrepresentations and omissions as to the safety, quality, purity, identity, and strength of the at-issue drugs, Plaintiffs would not have paid for those drugs. *Id.* ¶¶ 6, 9, 178. As in *In re Avandia*, Plaintiffs' injury does not depend on the at-issue drugs' ineffectiveness, or factual speculation concerning future events, but rather on GSK's misrepresentations concerning the production, quality, and safety of the drugs.

The parties agree the *In re Avandia* court held a plaintiff may adequately plead economic harm independent of whether the alleged fraud causes physical harm to the drug users. GSK,

[9] Defendants argue *In re Warfarin*, an antitrust case, is inapplicable to RICO claims. Def.'s Reply Mem. in Supp. of its Mot. to Dismiss 5 (citing *In re Schering-Plough Corp.*, 2009 WL 2043604, at *21; *Dist. 1199P*, 2008 WL 5413105, at *6). The Third Circuit, however, found *In re Warfarin* applicable in *In re Avandia*, a RICO case, because "RICO's standing requirements were modeled on antitrust law." 804 F.3d at 649 n.32.

however, attempts to distinguish *In re Avanadia* by arguing that whereas the plaintiffs in that case alleged GSK's misrepresentations regarding the at-issue drug's safety profile led to higher prices (the price effect) and an increase in the quantity of drugs prescribed by physicians (the quantity effect), here Plaintiffs merely allege the at-issue drugs were rendered adulterated and worthless due to cGMP violations at the plant, but fail to allege how non-disclosure of the violations had any bearing on the quality of the drugs. GSK notes that according to the FDA, "adulterated" does not mean the drugs were ineffective, unsafe, or otherwise caused harm; rather, the term is merely a regulatory designation relating to conditions at the plant where the drug is manufactured, and the drugs may still meet their labeled specifications. Def.'s Mot. to Dismiss 17-18; Def.'s Mem. Concerning *In re Avandia* 5-6. GSK thus argues Plaintiffs' description of the drugs as "worthless" is unfounded, and, therefore, so is their economic harm.[10]

The law is unclear as to the extent to which cGMP violations, by themselves, affect a drug's worth.[11] According to the FDA, drugs produced under conditions that do not comply

[10] The fact that Plaintiffs alleged not overpayment, as in *In re Avandia*, but payment they would have not made at all due to the "worthlessness" of the at-issue drugs is of no import. In *In re Avandia*, GSK argued the plaintiffs' claim that doctors relied on GSK's misrepresentations when prescribing the at-issue drug failed because there was no allegations that an alternative prescription would have been cheaper. 804 F.3d at 644-45. The Third Circuit rejected that argument, noting the plaintiffs' injury was not entirely contingent on the existence of cheaper alternative drugs because under plaintiffs' "excess price" theory, they could show the at-issue drug cost too much regardless of whether cheaper drugs existed on the market. *Id.* at 645.

[11] Defendants cite several cases for the proposition that cGMP violations alone are insufficient to show a drug is defective and, therefore, resulted in economic harm to the party paying for the drug. However, the cases were decided before *In re Avandia*. They are also distinguishable on their facts and the standard applied. *See In re McNeil Consumer Healthcare*, 877 F. Supp. 2d 254, 271 (E.D. Pa. 2012) (finding plaintiffs who purchased non-recalled drugs but "claimed their losses arose at the time of sale because they paid premium prices for products that were manufactured at facilities with quality control problems" and relied on "experiences of other individuals" who suffered adverse effects failed to state a cognizable injury); *Polk v. KV Pharm. Co.*, No. 4:09-CV-00588 SNLJ, 2011 WL 6257466, at *5-6 (E.D. Mo. Dec. 15, 2011) (holding consumer-plaintiff's "conclusory allegation that [a drug] was adulterated and therefore

with cGMPs may nevertheless meet their labeled specifications and be fit for consumption. *See* FDA, *Facts About the Current Good Manufacturing Practices (CGMPs)* (2015), http://www.fda.gov/D rugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm (last visited Oct. 26, 2016) ("If a company is not complying with CGMP regulations, any drug it makes is considered 'adulterated' under the law. This kind of adulteration means that the drug was not manufactured under conditions that comply with CGMP. It does not mean that there is necessarily something wrong with the drug."). Regardless of whether the at-issue drugs were fit for consumption, 21 U.S.C. § 331(a) prohibits the introduction of adulterated drugs into interstate commerce, and Plaintiffs allege the at-issue drugs were rendered worthless because they were sold illegally. *See* Compl. ¶ 6-9.

Moreover, because "the impact of CGMP violations depends on the nature of those violations and on the specific drugs involved," FDA, *Facts About the CGMPs*, Plaintiffs are entitled to prove that the nature of GSK's violations had a material impact on the drugs for which they paid.[12] Even if "adulterated" is not interchangeable with "unsafe" or "ineffective," the *In re Avandia* court held an at-issue drug does not itself have to be defective, but rather the plaintiffs

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worthless" did not support the inference that the drug "was anything less than what it purported to be," where the allegation was based solely on a FDA consent decree in which the defendant disclaimed any liability); *In re Digitek Prod. Liab. Litig.*, 821 F. Supp. 2d 822, 835-36 (S.D. W. Va. 2011) (granting summary judgment in product defect case in favor of defendants where evidence showed only single defective tablet was released, and drug recall and ongoing cGMP violations were insufficient to give rise to a reasonable inference that the drug reached the market and caused harm to plaintiffs); *Myers-Armstrong v. Actavis Totowa, LLC*, No. C 08-04741 WHA, 2009 WL 1082026, at *4 (N.D. Cal. Apr. 22, 2009) (dismissing consumer-plaintiff's claims because the mere fact that the drug was adulterated due to cGMP violations was insufficient to allege a cognizable injury absent a "manifestation of a defect that results in some injury or rational fear of injury") *aff'd*, 382 F. App'x 545 (9th Cir. 2010).

[12] An overview of the specific nature of the problems that occurred at the Cidra plant can be found in paragraph 77 of the Complaint. These problems are subsequently addressed in exhaustive detail between paragraphs 111-174.

had to show the masking of safety risks affected its value. Although Plaintiffs here do not allege the same "excess price" and "quantity effect" theories put forth by the *In re Avandia* plaintiffs, they do put forth a theory, with supporting facts, that includes elements of both theories: GSK's non-disclosure rendered the at-issue drugs *worthless* and physicians would have not prescribed the at-issue drugs *at all* had GSK not concealed the cGMP violations because Plaintiffs would not have placed the drugs on the their formularies. The alleged effect is supported by Plaintiffs' allegations of numerous issues with the at-issue drugs' safety and effectiveness, including product mix-ups, product contamination, failure in content uniformity, and foreign particles found in certain drug products, as admitted by SB Pharmco pursuant to its guilty plea. *See* Compl. ¶ 132; U.S. Dept. of Justice, Oct. 26, 2010 Press Release, https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-pay-750-million-resolve-criminal-and-civil-liability-regarding; Guilty Plea Settlement Agreement at 3-4, https://www.justice.gov/archive/usao/ma/news/2010/October/GSK%20Settlement%20Agreement10_26.pdf. Thus, contrary to GSK's assertion, Plaintiffs have adequately connected GSK's non-disclosure of cGMP violations, and the effect of those violations, on the quality and packaging of certain at-issue drugs, to Plaintiffs' payment for drugs they allege had no value.

GSK argues that of the alleged cGMP issues, only the aforementioned four quality issues—product mix-ups, product contamination, failure in content uniformity, and foreign particles found in certain drug products—related directly to the quality or packaging of the finished drug products; the remaining allegations relate to allegedly deficient manufacturing processes and procedures at Cidra. Of those four, GSK argues, Plaintiffs failed to allege they paid for the drugs or that they were distributed into the market. Plaintiffs respond that those four

issues are illustrative, not exclusive, and merely demonstrate the nature of GSK's FDA violations.

Again, because the Court finds it premature to dismiss Plaintiffs' claims based solely on cGMP violations, the fact that only four of the alleged cGMP violations are directly quality-related is not fatal. Furthermore, although GSK is correct that Plaintiffs did not specifically allege they paid for the drugs from the affected lots, they reiterate throughout the Complaint that they paid for the "adulterated" at-issue drugs. *See, e.g.*, Compl. ¶¶ 3, 4, 6, 9, 10, 185, 194. They also characterize themselves as the "principal payers" for the at-issue drugs, *id.* ¶ 182, noting they "collectively represent approximately 70% of the U.S. market for non-governmental health insurance," *id.* ¶ 3; "paid billions of dollars for [the] adulterated drugs . . . manufactured at [the Cidra plant]," *id.*; and "were the biggest single source of GSK's revenues in the U.S. market" from the at-issue drugs, *id.* ¶ 10. Thus, Plaintiffs have plausibly alleged they paid for affected lots of the at-issue drugs, giving rise to their economic injury.

Further, contrary to GSK's contention that Plaintiffs failed to allege the drugs from the affected lots were released to the market, they did allege some of those drugs were released. *See* Compl. ¶ 112 (noting approximately 17 complaints Cidra received in 2002 and 2003 regarding product commingling of Avandia, Paxil, and Coreg); *id.* ¶ 126 (noting SB Pharmco admitted in its guilty plea that in 2003, it "released . . . lots of Kytril that were deemed adulterated because the manufacturing processes and laboratory testing were insufficient to assure the Kytril was of the quality and purity that Kytril was represented to possess"); *id.* ¶ 128 (noting contaminated Bactroban ointment released to market in 2002); *id.* ¶ 131-32 (describing continued distribution of contaminated Bactroban to the market in 2003); *id.* ¶ 154 ("[I]n September 2004, Cidra rejected a batch of Avandamet due to OOS results in the content uniformity of the rosiglitazone

active ingredient, but failed to investigate and released to the market 26 other batches made with the same batch of rosiglitazone."); *id.* ¶ 157 (alleging SB Pharmco admitted it released to the market adulterated Avandamet that was not of the "strength, identity, quality and purity [it] was represented to possess").

Considering the facts alleged bearing on Plaintiffs' economic injury—the cGMP violations, quality of drug issues, FDA seizure of stocks of adulterated drugs, and the existence of a permanent injunction preventing GSK from directly or indirectly introducing or delivering into interstate commerce adulterated product from the Cidra plant in April 2005—Plaintiffs have sufficiently pleaded they suffered injury to their businesses as a result of paying for the adulterated at-issue drugs.

C. Statute of Limitations

GSK next argues all of Plaintiffs' claims are barred by the applicable two-or four-year statute of limitations.[13] Plaintiffs allege their injuries arose between 1997 and 2006. Compl. ¶ 12. Because Plaintiffs filed their suit on July 15, 2011, their claims are timely only if their claims accrued on or after July 15, 2007 for claims subject to a four-year statute of limitations, and on or after July 15, 2009 for claims subject to a two-year statute of limitations. GSK argues because Plaintiffs had ample notice of the cGMP violations at the Cidra plant before July 15,

[13] The limitations periods applicable to Plaintiffs' claims are as follows: (1) RICO claims are subject to a four-year statute of limitations, *see Cetel v. Kirwan Fin. Grp., Inc.*, 460 F.3d 494, 506 (3d Cir. 2006); (2) claims for common law fraud are subject to a two-year statute of limitations, *see Beauty Time, Inc. v. VU Skin Systems, Inc.*, 118 F.3d 140, 143 (3d Cir. 1997) (citing 42 Pa. Cons. Stat. § 5524(7)); (3) claims for statutory civil insurance fraud are subject to a two-year statute of limitations, *see State Farm Mut. Auto. Ins. Co. v. Midtown Med. Ctr. Inc.*, 2005 WL 627969, at *3 (E.D. Pa. 2005); (4) unjust enrichment claims are subject to a four-year statute of limitations, *Harry Miller Corp. v. Mancuso Chemicals Ltd.*, 469 F. Supp. 2d 303, 319 (E.D. Pa. 2007); (5) negligent misrepresentation claims are subject to a two-year statute of limitations, *see Cooper v. Sirota*, 37 F. App'x 46, 48 (3d Cir. 2002); and (6) breach of warranty claims are subject to a four-year statute of limitations, *Gunsalus v. Celotex Corp.*, 674 F. Supp. 1149, 1154-55 (E.D. Pa. 1987).

2011, they knew or should have known of their claims before that date and their claims are therefore time-barred.

A district court may consider a limitations defense on a motion under Rule 12(b)(6) "only if the time alleged in the statement of a claim shows that the cause of action has not been brought within the statute of limitations." *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014) (internal quotation marks and citation omitted). However, "if the bar is not apparent on the face of the complaint, then it may not afford the basis" for dismissal. *Id.*

Pennsylvania's discovery rule "tolls the accrual of the statute of limitations when a plaintiff is unable, 'despite the exercise of due diligence, to know of the injury or its cause.'" *Mest v. Cabot Corp.*, 449 F.3d 502, 510 (3d Cir. 2006) (quoting *Pocono Int'l Raceway v. Pocono Produce, Inc.*, 468 A.2d 468, 471 (Pa. 1983)). "For the statute of limitations to run, a plaintiff need not know the 'exact nature' of his injury, as long as it objectively appears that the plaintiff 'is reasonably charged with the knowledge that he has an injury caused by another.'" *Id.* at 510-11 (quoting *Ackler v. Raymark Indus., Inc.*, 551 A.2d 291, 293 (Pa. 1988)). "A plaintiff therefore is obligated to exercise reasonable diligence in ascertaining the existence of the injury and its cause." *Id.* at 511 (internal quotation marks and citation omitted).

Similarly, in terms of RICO's four-year statute of limitations, the Third Circuit has held courts should apply an injury discovery rule "whereby a RICO claim accrues when plaintiffs knew or should have known of their injury." *Cetel*, 460 F.3d at 507 (internal quotation marks and citations omitted). When plaintiffs should have known the basis of their claims "depends on whether [and when] they had sufficient information of possible wrongdoing to place them on 'inquiry notice' or to excite 'storm warnings' of culpable activity." *Id.* (quoting *Benak ex. rel. Alliance Premier Growth Fund v. Alliance Capital Mgmt. L.P.*, 435 F.3d 396, 400 (3d Cir.

2006)). "Moreover, plaintiffs have inquiry notice 'whenever circumstances exist that would lead a reasonable investor of ordinary intelligence, through the exercise of due diligence, to discovery of his or her injury.'" *Id.* (quoting *Matthews v. Kidder Peabody & Co.*, 260 F.3d 239, 252 (3d Cir. 2001)). A court's analysis of inquiry notice involves two steps: (1) defendant must show the existence of "storm warnings";[14] and (2) plaintiffs then must show that, "heeding the storm warnings, they exercised reasonable diligence but were unable to find and avoid the storm." *Id.*

GSK argues Plaintiffs were, or should have been, aware of their claims by 2003, or by early 2005 at the latest, due to the series of public disclosures of the cGMP issues at the Cidra plant, including (1) the FDA's recall of select lots of Bactroban, and issuance of a Warning Letter regarding cGMP violations in 2002; (2) the FDA's commencement of a criminal investigation of the Cidra plant in 2003, which was documented in pharmaceutical publications and the national media; (3) GSK's 2003 Annual Report, disclosing that the FDA issued two Forms 483[15] to Cidra; (4) the FDA's seizure in March 2005 of all stocks of Avandamet, which

[14] "Storm warnings" include "any information or accumulation of data that would alert a reasonable person to the probability that misleading statements or significant omissions had been made." *Cetel*, 460 F.3d at 507. "This charge saddles the investor with responsibilities like reading prospectuses, reports, and other information related to the investments, and, additionally, assumes knowledge of publicly available news articles and analyst's reports." *Id.* (internal quotation marks and citations omitted).

[15] The FDA describes a Form 483 as follows:

> An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts. . . . Observations are made when in the investigator's judgement, conditions or practices observed would indicate that any food, drug, device or cosmetic has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health. . . . Companies are encouraged to respond to the FDA Form 483 in writing with their

was widely publicized in the media and disclosed in GSK's annual reports; and (5) publicity following the April 2005 Consent Decree between GSK and the United States, discussing the issues at Cidra, the March 2005 seizure, and the terms of the consent decree.[16]

In response, Plaintiffs contend GSK has failed to carry its heavy burden of proof in establishing their claims are time-barred for three reasons. Pls.' Opp'n 15 (citing *Van Buskirk v. Carey Canadian Mines, Ltd.*, 760 F.2d 481, 498 (3d Cir. 1985)). First, they assert the public record between 2002 and 2005 is insufficient to show they had inquiry notice regarding the probability of alleged injury, as any problems at the plant were confined to specific drugs and/or batches of drugs, the FDA allowed the plant to continue operating, and GSK assured the public it was cooperating fully with the FDA. In fact, they assert the public had no notice of the truth regarding the Cidra plant until GSK announced its global settlement of Eckard's qui tam case[17] and SB Pharmco's guilty plea in October 2010. Second, even if Plaintiffs were on inquiry notice, further inquiry would have been fruitless. Plaintiffs argue they could not have independently discovered the extent of the issues at the Cidra plant because GSK was actively

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> corrective action plan and then implement that corrective action plan expeditiously.

FDA Form 483 Frequently Asked Questions, http://www.fda.gov/ICECI/Inspections/ucm256377.htm (last visited Nov. 7, 2016).

[16] In making their arguments regarding inquiry notice, the parties rely on news articles and GSK's annual reports, which they attach as exhibits. It is not clear whether the Court may consider those exhibits at this stage. However, even considering such documents, the Court cannot decide the applicable statutes of limitations bar Plaintiffs' claims at this stage.

[17] Plaintiffs assert the *Eckard* case was filed under seal in 2004 and was not unsealed until July 16, 2007, less than four years before they filed suit in July 2011. Further, Plaintiffs assert the case remained unpublicized until 2010, except for brief one-sentence references to the case in GSK's annual reports beginning in 2007. For example, in its 2007 Annual Report, published in 2008, GSK stated only that "in July 2007, the Group learned that the US District Court for the District of Massachusetts had unsealed a complaint brought by a former employee under the federal False Claims Act," i.e., the *Eckard* case.

concealing them from the FDA. At minimum, Plaintiffs argue, the question whether additional inquiry would have been fruitful is an unresolved factual issue. Third, GSK's fraudulent concealment[18] of those conditions tolled the limitations period.

The Court cannot conclude that Plaintiffs knew or should have known the extent of GSK's misrepresentations regarding the cGMP violations at Cidra and the resulting issues concerning the quality and safety of the at-issue drugs at any time before July 11, 2007. Factual issues remain as to whether the public disclosures of cGMP issues between 2002 and 2005 constituted "storm warnings" establishing inquiry notice, especially in light of GSK's attempts to minimize the extent of the cGMP violations, the violations' effect on the quality and safety of the drugs produced at Cidra, and the FDA's involvement.[19] *See Mathews v. Kidder, Peabody & Co.*,

[18] Under the doctrine of fraudulent concealment, "a corollary to the discovery rule," the statute of limitations is tolled where a plaintiff proves by "clear, precise and convincing evidence" that "through fraud or concealment the defendant cause[d] the plaintiff to relax his vigilance or deviate from the right of inquiry." *Bohus v. Beloff*, 950 F.2d 919, 925 (3d Cir. 1991) (citation omitted). "There must be an affirmative and independent act of concealment that would divert or mislead the plaintiff from discovering the injury." *Id.* Once fraudulent concealment is established, "the statute of limitations is tolled until the plaintiff knew or using reasonable diligence should have known of the claim." *Id.* at 925-26 (internal quotation marks and citation omitted); *see also In re Schering-Plough Corp. Intron*, 2009 WL 2043604, at *22 ("In addition, Plaintiffs' allegation that Defendants concealed their illegal conduct raises the possibility that the applicable statutory periods should be tolled and, by implication, creates an additional hurdle to establishing that the RICO claims are barred.").

[19] Defendants argue "extensive publicity" of the cGMP issues would have caused a reasonable insurance company to conduct further investigation, citing *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Product Liability Litigation*, 352 F. Supp. 2d 533 (E.D. Pa. 2004). In that case, however, the district court found a consumer of a certain diet drug had inquiry notice of her potential claims following extensive publicity of the drug's recall, including (1) "leading stories on major television network news programs;" (2) a "front-page story [in *USA Today*] regarding the withdrawal of [the] drugs, its effects, . . . the response by various organizations throughout the United States regarding the news," and "potential [imminent] litigation"; (3) the defendant's efforts to notify consumers about the recall through press releases, full-page ads in leading national and regional newspapers, and a "'Dear Health Care Provider Letter" to approximately 450,000 physicians and pharmacists in which it informed them of the withdrawal of the drug from the market and of the potential association between use of the drugs

260 F.3d 239, 253 (3d Cir. 2001) ("[W]e are mindful of the dangers in adopting too broad an interpretation of inquiry notice."); *In re Schering-Plough Corp. Intron*, 2009 WL 2043604, at *22 ("[I]t is not clear that the FDA warning letter, public filings and newspaper articles reporting the Government's investigation . . . provided warnings sufficient to put Plaintiffs on notice of their purported RICO claims . . . ."); *Stafford Inv. LLC v. Vito*, Nos. 04-3182, 06-1112, 06-4424, 2008 WL 5062136, at *3 (E.D. Pa. Dec. 1, 2008) ("Unless there is a clear basis for the court to determine when plaintiff knew or should have known of the existence of her cause of action, the issue of whether the plaintiff had a reasonable opportunity to discover the violation is a question to be resolved by a jury.").

For example, the Bactroban recall in 2002 was followed by only an FDA Warning Letter advising of cGMP violations. In 2003, the FDA opened a criminal investigation of the Cidra plant and executed search warrants at the facility. However, although GSK argues the investigation was documented in "pharmaceutical publications and the national media," Def.'s Mot. to Dismiss 23, the coverage was extremely minimal and vague as to the nature or extent of the investigation.[20]

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and instances of valvular heart disease'"; and (4) the "comprehensive publicity campaign surrounding the nationwide class action Settlement Agreement with [the defendant]." *Id.* at 538-39. Furthermore, the court noted the plaintiff in that case admitted she had inquiry notice of a problem potentially related to the diet drug in her deposition. *Id.* at 538. The publications and news coverage in this case fall short of such "extensive publicity" and outreach efforts.

[20] The coverage included (1) a 140-word *Drug Industry Daily* article noting that although the "FDA ha[d] begun an investigation into manufacturing issues at [GSK's] facility in Cidra, Puerto Rico," the FDA "did not tell GSK the specific nature of the investigation," and GSK "would not interrupt the supply from the plant," *see* Def.'s Mot. to Dismiss, Ex. 10; (2) an article in *The Guardian*, "Glaxo plant in Puerto Rico under FDA scrutiny," which noted GSK was uninformed about the specific nature of the FDA's investigation, and quoted finance director John Coombe as stating, "'The issues raised [in the FDA's Warning Letter] were fully resolved and closed up. The FDA are now back. They are being quite coy about exactly what they are looking for,'" *id.*, Ex. 9; (3) a 253-word article from *HIS Global Insight*, "GSK Plant in Puerto Rico Faces FDA

Although the FDA's March 2005 seizure of all stocks of Avandamet (and Paxil CR), and subsequent Consent Decree, was widely covered in the news media, GSK continued to downplay the extent of its issues and assure the public of its compliance with FDA demands. In its 2004 Annual Report, published in 2005, GSK noted the FDA's inspection of the Cidra plant in November 2004 and subsequent issuance of two Forms 483 containing "observations relat[ing] to certain aspects of production controls, process validation and laboratory investigations." Def.'s Mot. to Dismiss, Ex. 14. The Report further stated, "In response to the FDA's observations, the Group, among other things, voluntarily recalled certain shipments of Paxil CR and Avandamet from wholesalers. In March 2005 the FDA initiated seizures of Paxil CR and Avandamet tablets manufactured at Cidra on grounds that those products failed to meet FDA manufacturing standards. The Group continues to cooperate with the FDA in responding to [its] observations . . . ." *Id.* In an April 2005 *New York Times* article describing the Consent Decree, GSK's global chief of pharmaceuticals reported GSK "was able to resolve the issue [of the drug recalls] quickly because of its strong relationship with the F.D.A." *Id.*, Ex. 36.

GSK presented the same sentiments of resolution in its annual reports. The 2005 and 2006 Annual Reports each provided a single sentence regarding the recall ("In March 2005 the FDA halted distribution of supplies of Paxil CR and Avandamet due to manufacturing issues."), followed by a description of the Consent Decree: the "Consent Decree provides for an independent expert to review manufacturing processes at the site for compliance with [GMP] requirements," requires GSK to "provide[] a report to the FDA on the deficiencies identified in

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Manufacturing Probe," noting " it remains unclear precisely what the FDA is investigating;" *id.*, Ex. 11; and (4) a 274-word article from the Glasgow *Herald*, "Glaxo pre-tax profits climb 22% to (pounds) 1.7bn," which references the investigation in a single line noting "investors were also unnerved by news that the [FDA] was investigating a Glaxo factory in Puerto Rico," *id.*, Ex. 12.

[its] review, setting out a corrective plan and timetable for completion," and imposes "no financial penalties." *Id.*, Ex. 15 & 16. The 2006 Annual Report further states that "[i]n June 2006, the FDA confirmed that the status for the site has been upgraded to 'voluntary action indicated,' which means that the FDA deems the [Cidra plant] acceptable for the export of products and for routine manufacturing operations." *Id.*, Ex. 16. GSK continually noted its "commit[ment] to working cooperatively with the FDA to address any issues in a timely fashion." *Id.*, Ex. 15 & 16. In its 2007 Annual Report, GSK noted, "In March 2007, the FDA completed a general GMP inspection which resulted in four inspectional observations. The Group has been advised by the FDA that the Group's response to the inspectional observations is satisfactory." Pl.'s Opp'n, Ex. B.

Because factual issues remain as to whether Plaintiffs were on inquiry notice that the at-issue drugs were adulterated, and if inquiry notice existed, whether Plaintiffs exercised due diligence, GSK's motion to dismiss Plaintiffs' claims as time-barred is denied.

Just as the Court finds it premature to decide whether Plaintiffs' were on inquiry notice as to their claims prior to July 2007, an inquiry into whether GSK fraudulently concealed those claims similarly would be premature. *See Hoppe v. SmithKline Beecham Corp.*, 437 F. Supp. 2d 331, 336-38 (E.D. Pa. 2006) ("In cases involving tolling due to allegations of fraudulent concealment, the Third Circuit has encouraged and approved of allowing the factual record to be sufficiently developed before reaching the issue." (citing *Byrnes v. De Bolt Transfer, Inc.*, 741 F.2d 620, 626-27 (3d Cir.1984), and *Urland v. Merrell–Dow Pharm., Inc.*, 822 F.2d 1268, 1276-77 (3d Cir.1987))). Further discovery is necessary to reveal whether GSK affirmatively

concealed information that misled Plaintiffs, and whether Plaintiffs in turn exercised reasonable due diligence to stay apprised of potential wrongdoing on the part of GSK prior to 2007.[21]

Because Plaintiffs have adequately pled an injury for the purposes of standing, and there remain legitimate questions of fact as to whether Plaintiffs had a reasonable opportunity to discover GSK's alleged fraudulent conduct underlying their claims, GSK's motion to dismiss Plaintiffs' claims is denied.

An appropriate Order follows.

BY THE COURT:

/s/ Juan R. Sánchez
Juan R. Sánchez, J.

[21] GSK argues Plaintiffs' breach of warranty claims are barred by the statute of limitations because the discovery rule does not apply to such claims. Def.'s Mot. to Dismiss 25-26 (citing 13 Pa. Cons. Stat. §§ 2725(a)-(b), 5525(a)(2)); *see also Gunsalus*, 674 F. Supp. at 1154-55 (discovery rule does not toll statute of limitations on breach of warranty claims unless there is an explicit warranty of future performance). In response, Plaintiffs argue fraudulent concealment equitably tolls the limitations period for warranty claims, as it does for their other claims. Pls.' Opp'n 27 n.23 (citing *In re Ford Motor Co. E-350 Van Prods. Liab. Litig.*, No. 03-4558, 2008 WL 4126264, at *18-19 (D.N.J. Sept. 2, 2008), and *Connaught Labs., Inc. v. Lewis*, 557 A.2d 40, 43-44 (Pa. Cmmw. Ct. 1989)). Because the Court will not decide whether fraudulent concealment tolls the statute of limitations, the question of whether Plaintiffs' breach of warranty claims are barred is also left for another day.